REMARKS

Claims 1, 3-11 and 14-47 were previously pending in the application; Claims 3, 10, 11, 16-28 and 34-37 have been withdrawn from consideration. In this response, independent Claims 1 and 29 are amended to further clarify the recitations of the claims, and Claim 48 is newly added. Thus, Claims 1, 3-11 and 14-47 are currently pending in the application, and Claims 1, 4-9, 14, 15, 29-33 and 38-48 are under consideration. Support for the amendments is found, for example, at Page 9, Paragraph 1 to Page 13, Paragraph 1 and Figures 1A-4B of the specification. No new matter has been introduced. Reconsideration of the pending claims in light of the following remarks is respectfully requested.

The Examiner has rejected Claims 1, 4-9, 14, 15, 29-33, and 38-47 under 35 U.S.C. §103(a) as allegedly unpatentable over U.S. Patent No. 6,117,147 to Simpson (hereinafter "Simpson") in view of U.S. Patent No. 6,743,243 to Roy et al., (hereafter "Roy") and further in view of U.S. Patent No. 6,726,923 to Iyer, et al. (hereafter "Iyer").

Applicants respectfully submit that the rejection is overcome in light of the following remarks.

Claim 1 recites a device for creating an anastomosis between first and second anatomical vessels. The device includes, *inter alia*, a substantially cylindrical extravascular body at least partially formed by a resorbable sponge material, a first securing means for securing an end of the first anatomical vessel to the body, and a second securing means for securing a portion of the second anatomical vessel to the body. The body includes an inner surface defining a through opening configured to receive at least a portion of the first anatomical vessel. Significantly, the body further includes a proximal flat surface configured to appose an outer surface of the second anatomical vessel, a distal surface distanced from the outer surface of

the second anatomical vessel and a straight side surface connecting the proximal surface and the distal surface, thereby providing a uniform outer diameter of the cylindrical body.

The through opening extends from the proximal surface to the distal surface. The first securing means is disposed on the inner surface of the body, for adhesively securing at least an end of the first anatomical vessel to the inner surface. The second securing means is adapted to secure the outer surface of the second anatomical vessel to the proximal surface of the cylindrical body, such that a hole formed in the outer surface of the second anatomical vessel is in fluid communication with the end of the first anatomical vessel.

Claim 29 is directed to a method for creating an anastomosis between first and second anatomical vessels. Claim 29 recites, *inter alia*, the step of handling a substantially cylindrical extravascular body as recited in Claim 1.

Similarly, new independent Claim 48 recites, *inter alia*, a substantially cylindrical extravascular body at least partially formed by a resorbable sponge material. The cylindrical body includes, *inter alia*, an inner curved surface defining an opening configured to receive at least a portion of the first anatomical vessel and an outer curved surface defining a uniform diameter of the body. The cylindrical body further includes, *inter alia*, an axis, a proximal end and a distal end. The proximal end and the distal end each include a flat surface perpendicular to the axis of the cylindrical body, the flat surface of the proximal end being configured to attach to an outer surface of the second vessel.

The claimed invention contemplates a device and method for creating an end-to-side anastomosis between a graft vessel and a target vessel, eliminating the need for suturing the graft vessel to the target vessel, while still maintaining the reliability and structural strength of the anastomosis. Specifically, the cylindrical body, having a uniform diameter from the

apposing surface to the distal surface, provides a solid structural support for the graft vessel, thereby preventing the graft vessel from undesirable swinging or moving relative to the target vessel, which is preferred in a cardiac surgical procedure, such as a coronary artery bypass surgery.

Simpson is directed to a device (14) for creating an end-to-side anastomosis. The device includes a tubular body (16), and a cuff (18) disposed at the lower end of the tubular body and configured to appose an outer surface of a target vessel. Simpson also teaches that the cuff has an adhesive surface for affixing the cuff to a target vessel. The device of Simpson does not have a cylindrical body having a uniform diameter, which has been acknowledged by the Examiner.

However, the Examiner asserts that Iyer discloses a cylindrical anastomosis support device having a uniform diameter. The Examiner has further cited U.S. Patent No. 6,176,864 to Chapman (hereinafter "Chapman") for the alleged teaching of a support device used in end-to-side anastomosis, which includes a cylindrical body having a uniform diameter. Based on the alleged teaching of Iyer and Chapman, the Examiner asserts that it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify the device of Simpson to have a uniform diameter since such configuration is well known in the art, as disclosed by Iyer, and since it has been held that changing the shape of a working part involves only routine skill in the art.

Applicants respectfully disagree with the Examiner's above assertion for at least the following reasons.

Iyer discloses a prosthetic device (26) adapted for delivering drugs. The prosthetic device is employed to prevent or suppress the possible failure of vascular grafts caused

by the proliferation and migration of smooth muscle cells resulting in intimal hyperplasia in the blood vessel or the adjacent graft orifice. Specifically, the device of Iyer is a dual layer prosthetic device externally wrapped or placed around the outer surface of a blood vessel or a graft (*see* Col. 10, Line 65 to Col. 11, Line 20 of Iyer). As shown in FIG. 7 of Iyer, the device (26) includes a first tubular portion wrapped around a venous structure (28) and a second tubular portion, integral with the first tubular portion, wrapped around an arterial structure (30) intersecting the venous structure. Accordingly, the first tubular portion and the second tubular portion intersect each other.

Thus, Iyer teaches an anastomosis device, in the form of a combination of two intersecting tubular portions, which is not a cylindrical body including a flat apposing surface, a distal surface distanced from the apposing surface and a straight side surface connecting the flat apposing surface and the distal surface, thereby defining a uniform diameter of the body, as recited in Claims 1 and 29 of the present application.

Furthermore, Applicants respectfully submit that one of ordinary skill in the art would understand that, collectively, the first tubular portion and the second tubular portion are the minimum set required to create an end-to-side anastomosis. Thus, the skilled artisan would not separately consider either the first portion or the second portion as cylindrical.

Therefore, the hypothetical combination of Simpson and Iyer does not teach or suggest a cylindrical extravascular body, as recited by Claims 1 and 29 of the present application.

Chapman discloses an anastomosis device for use in coupling an end of a graft vessel to a side of a target vessel. The device includes an elongated tubular member (70), through which the graft vessel extends. The distal end of the graft vessel, extending over the distal end of the tubular member, is reverted over the distal end of the tubular member. During

operation, the tubular member is radially compressed for insertion of the distal end of the tubular member, as well as the distal end of the graft vessel, into the target vessel through an incision. The tubular member subsequently expands to allow the distal end of the graft vessel, already inserted into the target vessel, to engage the inner surface of the target vessel, thereby forming an anastomosis.

In this regard, the Examiner asserts, "though Chapman discloses a different type of connection to the target vessel, the device itself is fully capable of being secured to the outer surface of the vessel since the body has sufficient thickness for applying adhesives" (*see*, Page 4, Lines 12-14 of the Office Action).

Applicants respectfully disagree with the Examiner's above rationale.

Initially, Chapman does not teach an extravascular body since the distal portion of the elongated tubular member is inserted into the target vessel during operation. Furthermore, the Chapman device relies on the engagement between the target vessel and the graft vessel to implement a fluid communication therebetween. Thus, the elongated tubular member, as a conveyer and supporter of the graft vessel, is not adhered to the target vessel. Stately differently, the elongated tubular member of Chapman does not embody an extravascular member intended for creating an anastomosis by adhesively attaching both the graft vessel and the target vessel.

For convenience, the Examiner appears to dissect the tubular member from its operational environment, notwithstanding the fundamental distinctions between the tubular member of Chapman and the extravascular cylindrical body of the claimed invention. Applicants respectfully submit that it is improper to ignore Chapman's guidance on the characteristic of the elongated tubular member, and doing so is highly suggestive of hindsight reasoning by the Examiner.

In addition, there is no evidence of record to support the alleged motivation. Nowhere does Chapman teach or suggest that the tubular member would be used as an extravascular member for adhesively attaching both the target vessel and the graft vessel, merely because the Chapman tubular member has sufficient thickness for applying adhesives. Outside of the teachings in the Applicants' own disclosure, there appears to be no reasonable or rational basis to combine these references in order to achieve the claimed result.

Therefore, Applicants respectfully submit that the hypothetical combination of Simpson and Chapman is improper.

Roy is relied on for the alleged teaching of an adhesive for attaching a tubular member to a vessel. Without acquiescing to the propriety of the Examiner's interpretation of Roy, Applicants respectfully submit that the alleged teaching of Roy does not remedy the underlying deficiencies of Simpson, Iyer and Chapman.

In summary, none of Simpson, Iyer, Chapman and Roy, applied individually or in combination as alleged by the Examiner, teach or fairly suggest the combination of features recited in Claims 1 and 29, from which the other claims depend.

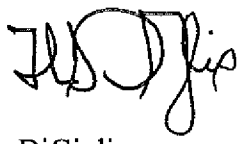
Accordingly, the rejection of Claims 1, 4-9, 14, 15, 29-33, ad 38-47 under 35 U.S.C. §103(a) based on the hypothetical combination of Simpson, Iyer, Chapman and Roy is overcome, and withdrawal thereof is respectfully requested.

Furthermore, Claim 48 recites an extravascular cylindrical body including an outer curved surface defining a uniform diameter of the cylindrical body and a flat surface of the distal end for attaching to the outer surface of the second anatomical vessel. Applicants respectfully submit that Claim 48 is patentably distinguished over the hypothetical combination

of Simpson, Iyer, Chapman and Roy for at least the foregoing reasons discussed with respect to Claims 1 and 29.

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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